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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,251

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Jean Taylor

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EXAMINER

WOODALL, NICHOLAS W

ART UNIT

PAPER NUMBER

3775

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,251	Applicant(s) TAYLOR, JEAN	
	Examiner Nicholas Woodall	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-21, 26-28, 33 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-21, 26-28, 33 and 35-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/05/2008 has been entered.

Allowable Subject Matter

2. The indicated allowability of claim 35 is withdrawn in view of the newly discovered reference(s) to Pasquet (U.S. Publication 2004/0117017). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner is unable to find support for the limitation directed to the lateral transmission elements towards each other that applies a

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compressive force to the wedge, ***which urges the first and second ends away from each other*** (emphasis added by the examiner). The specification does not appear to include this limitation and the limitation is not capable of being shown in the drawings. Therefore, the examiner is treating the claim as new matter since the limitation does not appear to part of the original disclosure.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 26, 28, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 26 describes a limitation wherein the releasing position is when the spinal column is extended and the compressive position is when the spinal column is in flexion is unclear to the examiner. Extension of the spinal column is known as the movement of the spine causing the spinous processes of the vertebrae to move closer together, i.e. bending backwards, and flexion of the spine is known as the movement of the spine causing the spinous processes of the vertebrae to move apart, i.e. bending forwards. Therefore, the examiner is unclear as to how the compressive lateral elements are compressed when the spine is in flexion and how the compressive lateral elements are not compressed when the spine is in extension. For examination purposes, the examiner will interpret the compressive position as the compressive lateral elements in compression, i.e. extension of the spine, and the releasing position as the compressive lateral elements not in compression, i.e. flexion of the spine.

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8. Claim 28 recites the limitation "the transverse direction" in lines 19-20. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 28, 33, 35, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pasquet (U.S. Publication 2004/0117017) in view of Taylor (U.S. Patent 6,626,944).

Pasquet discloses a device comprising an interspinous wedge (10) inserted between the spinous processes of two vertebrae, a strap engaged around the two spinous processes and the wedge, and first and second lateral transmission elements disposed between the strap and the wedge. The wedge includes a first end and a second opposite end, wherein each end comprises a recess bound by two lugs, wherein the recesses are shaped to receive the spinous processes and first and second lateral sides extending from the first end to the second end. The strap forms a first and a second compressive element disposed on opposite lateral sides of the wedge to maintain the position of the wedge. The lateral transmission elements include small bars (34) connected to a support plate, wherein the lateral transmission elements are disposed between the strap and the wedge and are capable of pressing against the middle of the lateral sides in a direction transverse to the longitudinal axis of the wedge

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and do not extend through a sagittal plane defined by the spinous processes in the space between the spinous processes. Pasquet fails to disclose the device wherein the wedge includes at least one elastically deformable zone. Taylor teaches an interspinous wedge manufactured from a multi-directionally flexible and elastic material including at least one elastically deformable zone in order to provide a device that allows the lugs to "self close" against the lateral faces of the spinous apophyses during compression (column 2 lines 4-20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the wedge of Pasquet manufactured from a multi-directionally flexible and elastic material including at least one elastically deformable zone in view of Taylor in order to provide a device that allows the lugs to "self close" against the lateral faces of the spinous apophyses during compression.

11. Claims 14-21, 26, 27, 36, 37, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree (U.S. Publication 2003/0220643) in view of Taylor (U.S. Patent 6,626,944) and Shirado (U.S. Publication 2003/0109880).

Ferree discloses a device comprising an interspinous wedge (110), two lateral elements (302, 303, 306, etc.) capable of being passed beneath the laminae of vertebra, and two lateral transmission elements (104;106). The wedge is inserted between the spinous processes of two vertebrae and includes first and second ends comprising a recess shaped to receive and engage the respective spinous processes, a longitudinal axis extending through the recesses, first and second lateral sides extending from the first end to the second end, and at least one elastically deformable zone, wherein the deformable zone has a limit of compressibility and a limit of

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deformation in the transverse direction that is reached at a predetermined tilted position.

The two lateral elements are disposed adjacent either lateral side of the wedge in a longitudinal direction, wherein the lateral elements are independent of each other with one end connected to a first vertebra and the opposite end connected to a second vertebra by anchorage pieces. The two lateral transmission elements are protuberances, i.e. bosses, disposed between the lateral elements and the wedge, wherein the lateral transmission elements are disposed entirely on the respective lateral side of the longitudinal axis, do not cross a sagittal plane defined by the spinous processes in the space between the spinous processes, and are capable of selectively pressing against the lateral sides of the wedge substantially midway between the first and second ends in the transverse direction near the elastically deformable zone.

Ferree fails to disclose the first end and the second end of the wedge including saddle-shaped recesses and the lateral elements being compressible elements. Taylor discloses an interspinous wedge (5) wherein the first and second ends include saddle shaped recesses (9) in order to receive the corresponding spinous processes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Ferree wherein the wedge further includes saddle-shaped recessed in the first and second ends in view of Taylor in order to receive the corresponding spinous processes.

Ferree discloses a device comprising lateral elements connected to two treated vertebra, for example Figure 3, in order to allow movement of the spinal joint. Shirado teaches a device comprising compressive lateral elements connected to two treated

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vertebra in order to allow movement of the spinal joint. Because both Ferree and Shirado teach device comprising lateral elements, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the one of the lateral elements with the other in order to achieve the predictable results of allowing movement of a spinal joint.

The device of Ferree as modified by Taylor as further modified by Shirado discloses a device wherein the compressive lateral elements are elastically deformable between a releasing position and a compressive position along an axis of the spine, wherein the compressible lateral elements are relatively closer to the wedge in the compressive position and wherein the compressible lateral elements are relatively spaced apart from the wedge in the releasing position.

Response to Arguments

12. Applicant's arguments with respect to claims 14-21, 26-28, 33, and 35-42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/

Examiner, Art Unit 3775

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733